

STELLA MARIS COLLEGE (AUTONOMOUS) CHENNAI –600 086
(For candidates admitted during the academic year 2023 – 2024 & thereafter)

M. Sc. DEGREE EXAMINATION, APRIL 2026
BIOTECHNOLOGY
FOURTH SEMESTER

COURSE : ELECTIVE
PAPER : IPR, BIOSAFETY, BIOETHICS AND ENTREPRENEURSHIP
SUBJECT CODE : 23BY/PE/IB15
TIME : 3 HOURS **MAX. MARKS: 100**

Q. No.	SECTION A Answer ALL Questions (10 x 1 = 10 marks)	CO	KL
1.	What is a Patent?	1	1
2.	What is a Geographical Indication (GI)?	1	1
3.	Define Good Laboratory Practices (GLP).	1	1
4.	What is a Biological Safety Cabinet (BSC)?	1	1
5.	What is Informed Consent in clinical trials?	1	1
6.	Define Gene Therapy.	1	1
7.	Define Project Appraisal.	1	1
8.	What is meant by Entrepreneurship?	1	1
9.	Define Market Research.	1	1
10.	Define New Product Development (NPD).	1	1
Q. No.	SECTION – B Answer ALL Questions (5 x 2 = 10 marks)	CO	KL
11.	Explain the significance of TRIPS agreement for India's IPR framework.	1	2
12.	Differentiate between Biosafety Level 1 (BSL-1) and Biosafety Level 2 (BSL-2).	1	2
13.	Explain the ethical concerns associated with human cloning.	1	2
14.	Explain the significance of a Project Report in entrepreneurship.	1	2
15.	Explain BIRAC's role in supporting startups.	1	2
Q. No.	SECTION C Answer ALL Questions (4 x 10 = 40 marks)	CO	KL
16.	Analyze the implications of the TRIPS Agreement on India. (OR) Give an account on patent infringement.	3	3
17.	Examine the significance of the Cartagena Protocol on Biosafety. (OR) Explain the ethical principles governing the phases of clinical trials.	3	3
18.	Explain how the technical, financial, market, and managerial appraisal contributes to evaluating the feasibility of a new venture. (OR) Analyse the content and significance of a Project Report in facilitating decision-making for investors and financial institutions.	4	4
19.	Analyse the role of biotechnology incubators, government funding mechanisms, and key sectors driving the Indian biotech industry. (OR) Discuss the types of entrepreneurs.	4	4

Q. No.	SECTION – D Answer ALL Questions (2 x 20 = 40 marks)	CO	KL
20.	Design a flowchart outlining the step-by-step process for filing a patent application in India under the Patents Act, 1970. (OR) Construct an ethical framework with regards to gene therapy.	4	5
21.	Explain the process of new product development from idea generation to commercialization and market research to funding strategies in a biotechnology company. (OR) Discuss biosafety levels for rDNA research.	5	6
